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| APPLICATION NO.                                                                   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/561,415                                                                        | 12/19/2005  | Shinji Nara          | 00005.001281        | 6544             |
| 5514 7590 06/29/2007<br>FITZPATRICK CELLA HARPER & SCINTO<br>30 ROCKEFELLER PLAZA |             |                      | EXAMINER            |                  |
|                                                                                   |             |                      | HAVLIN, ROBERT H    |                  |
| NEW YORK,                                                                         | NY 10112    |                      | ART UNIT            | PAPER NUMBER     |
|                                                                                   |             |                      | 1609                |                  |
|                                                                                   |             |                      |                     |                  |
|                                                                                   |             |                      | MAIL DATE           | DELIVERY MODE    |
|                                                                                   |             |                      | 06/29/2007          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Application No.                                                                                                                                             | Applicant(s)                                                               |  |  |  |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|--|--|--|
| ,                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 10/561,415                                                                                                                                                  | NARA ET AL.                                                                |  |  |  |
| Office Action Summary                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Examiner                                                                                                                                                    | Art Unit                                                                   |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Robert Havlin                                                                                                                                               | 1609                                                                       |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | The MAILING DATE of this communication app                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                             |                                                                            |  |  |  |
| Period fo                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | or Reply                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                             |                                                                            |  |  |  |
| WHIC<br>- Exter<br>after<br>- If NO<br>- Failu<br>Any                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DATES and the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. Operiod for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be timused, and will expire SIX (6) MONTHS from cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). |  |  |  |
| Status                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | ·                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                             |                                                                            |  |  |  |
| 1)⊠                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Responsive to communication(s) filed on 16 Ag                                                                                                                                                                                                                                                                                                                                                                                                   | <u>oril 2007</u> .                                                                                                                                          |                                                                            |  |  |  |
| 2a) <u></u> □                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | This action is <b>FINAL</b> . 2b)⊠ This                                                                                                                                                                                                                                                                                                                                                                                                         | action is non-final.                                                                                                                                        |                                                                            |  |  |  |
| 3)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                             |                                                                            |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                             |                                                                            |  |  |  |
| Dispositi                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | ion of Claims                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                             |                                                                            |  |  |  |
| 5) <u></u><br>6)⊠                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Claim(s) 1-20,26 and 27 is/are pending in the a 4a) Of the above claim(s) 1-10,26 and 27 is/are Claim(s) is/are allowed. Claim(s) 11-20 is/are rejected. Claim(s) is/are objected to. Claim(s) are subject to restriction and/or                                                                                                                                                                                                                | withdrawn from consideration.                                                                                                                               | ·                                                                          |  |  |  |
| Applicati                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | on Papers                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                             | •                                                                          |  |  |  |
| 9)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | The specification is objected to by the Examine                                                                                                                                                                                                                                                                                                                                                                                                 | r.                                                                                                                                                          |                                                                            |  |  |  |
| 10)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | The drawing(s) filed on is/are: a) ☐ acce                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                             |                                                                            |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Applicant may not request that any objection to the                                                                                                                                                                                                                                                                                                                                                                                             | • • • • • • • • • • • • • • • • • • • •                                                                                                                     | · ·                                                                        |  |  |  |
| 11)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Replacement drawing sheet(s) including the correct<br>The oath or declaration is objected to by the Ex                                                                                                                                                                                                                                                                                                                                          | •                                                                                                                                                           |                                                                            |  |  |  |
| Priority ι                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | ınder 35 U.S.C. § 119                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                             | •                                                                          |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul> |                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                             |                                                                            |  |  |  |
| Attachmen                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                 | A) 🗖 Intonian Sumana                                                                                                                                        | (PTO 413)                                                                  |  |  |  |
| 2) 🔲 Notic                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948)                                                                                                                                                                                                                                                                                                                                                             | 4) Interview Summary Paper No(s)/Mail Da                                                                                                                    | ate                                                                        |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | mation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date                                                                                                                                                                                                                                                                                                                                                                                    | 5) Notice of Informal P 6) Other:                                                                                                                           | atent Application                                                          |  |  |  |

Application/Control Number: 10/561,415

Art Unit: 1609

#### **DETAILED ACTION**

**Status of the claims:** Claims 1-20, 26 and 27 are currently pending. Amendments to the claims were filed on 4/16/07. Claims 1-10 were amended from a product to a method. Claims 11-20 and 25-27 were previously presented. Claims 21-25 and 28-31 were cancelled.

**Priority:** This application is a 371 of PCT/JP04/08494 filed on 06/10/2004 and claims foreign priority to JAPAN 2003185475 filed on 06/27/2003.

**IDS:** The IDS dated 6/22/06 was received and considered, however, the references were not provided in an acceptable format for the examiner to review. Therefore, none of the references cited in the form 1449 have been considered.

#### Election/Restrictions

# 1. Applicant's election of the species

2-[2-ethyl-3,5-dihydroxy-6-[3-methoxy-4-(2-piperidinoethoxy)benzoyl]phenyl]-N,N-bis(2-methoxyethyl)acetamide

Art Unit: 1609

and Group V with traverse in the reply filed on 4/16/07 is acknowledged. The traversal is on the ground(s) that the variable R1-R6 groups do not recite separately patentable inventions and that there is a "common shared novel technical feature". This is not found persuasive because as pointed out in the requirement for restriction US 7,074,770 teaches compounds that render the common technical feature not novel. Furthermore, the variable groups as defined read on groups such as morpholinyl, pyridinyl, and pyrazolyl each of which are art recognized different classes of compounds and thus result in patentably distinct compounds that are non-obvious variants. If the applicant considers these types of modifications on formula I and IA to be obvious variations, the examiner invites the applicant to specifically point out for the record what should be considered obvious variations.

In the applicant's response to the restriction requirement the elected species is a member of group I (*Group I, claim 10, drawn to a product of Formula I with all of the limitations of claim 10*) and NOT group V. Therefore, since the elected species clearly defines what the applicant considers to be their invention whereas the group definitions are less clear, the examiner has determined that the applicant elected group V in error and applicants intended to elect group I.

In accordance with the election of species as required in the requirement for restriction, the examiner has searched the elected species and found it to be free of the prior art. The examiner then expanded the search and found art when expanded beyond the following scope: claims 11-20, in part, drawn to products including compounds of formula (IA) wherein:

Application/Control Number: 10/561,415

Art Unit: 1609

R6A is hydrogen, lower alkyl, halogen or aryl

R3A, R4A, and R5A are hydrogen, and

R2A is an optionally substituted aryl.

The requirement is still deemed proper and is therefore made FINAL. Thus, claims 1-10 and 26-27 are withdrawn from consideration.

# Claim Objections

Claims 11-20 are objected to as reading on non-elected subject matter.

# Status of non-elected subject matter

If the claims were not restricted to the scope above, the 102 rejections in bullet 2 and 3 below would stand.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 3. Claim 11-13 and 15-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Hassall et al. (J. Chem. Soc., Perkin Transactions 1: Organic and Bio-Organic Chemistry, 1973, vol. 23, p. 2853-61).

Page 5

Application/Control Number: 10/561,415

Art Unit: 1609

$$\begin{array}{c|c} \text{OMe} & \text{OMe} \\ \text{O} & \text{OMe} \\ \text{OMe} & \text{OMe} \\ \text{OMe} & \text{C-NH-C} \\ \text{OMe} & \text{OMe} \\ \end{array}$$

Hassall et al. teaches

compound

which is a member of the

genus described by formula (IA):

where R3A and R5A are methyl; R4A

and R6A are hydrogen; nA is 1; R1A is 2,6-dimethoxybenzamide.

Furthermore, the examiner includes the following prior art reference for the record due to the similarities to the claimed subject matter:

Gosman et al. (Tetrahedron Letters, 1996, v. 37, no. 25, p. 4369-4372) teaches the

#### Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Application/Control Number: 10/561,415

Art Unit: 1609

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 11-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 10/584,234 and claims 1-39 of copending application 11/718,079. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter of the claims is substantially similar as described by formula I and the definition of the variable group substitutions results in claims that are coextensive in scope.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### Conclusion

All claims are rejected.

The examiner believes the applicants are using negative limitations or provisos to avoid prior art teachings within their broad genus, however the applicants have not included any such references in their IDS submission dated 6/22/2006. The examiner requests that the applicants provide these prior art references.

Art Unit: 1609

# Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Havlin whose telephone number is (571) 272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert Havlin Examiner

RH

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